

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:

*The County of Summit, Ohio, et al. v.
Purdue Pharma L.P., et al.*
Case No. 1:18-op-45090 (N.D. Ohio)

**MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster**

*The County of Cuyahoga, Ohio, et al. v.
Purdue Pharma L.P., et al.*
Case No. 1:17-op-45004 (N.D. Ohio)

**MEMORANDUM OF LAW IN SUPPORT OF
RITE AID OF MARYLAND'S
MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

Defendant Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Support Center (“Rite Aid” or “Rite Aid Mid-Atlantic”) stands apart from the other defendants, even from other Pharmacy Defendants. Although Plaintiffs’ claims against Rite Aid fail for many reasons equally applicable to other defendants, detailed in joint motions for summary judgment, Plaintiffs claims against Rite Aid fail for additional reasons: most obviously, a simple failure of proof.

Like their claims against other distributors, Plaintiffs’ claims against Rite Aid concern suspicious order monitoring. But Plaintiffs have presented no evidence of any deficiency in Rite Aid’s suspicious order monitoring system. Their experts who criticize other defendants’ suspicious order monitoring systems—Seth Whitelaw and James Rafalski—say nothing about Rite Aid’s systems. No evidence supports (and the uncontroverted evidence of Rite Aid’s expert rebuts) the core factual premise of Plaintiffs’ claims against Rite Aid.

Nor does Plaintiffs’ evidence show causation with respect to Rite Aid Mid-Atlantic, which distributed only a minuscule percentage of the opioids distributed in the two counties. No expert identifies any injuries caused by diversion from Rite Aid’s distribution of suspicious orders, much less opines that such diversion was a substantial factor in an indivisible injury.

Even if Plaintiffs have evidence that would permit their claims against other defendants to proceed to trial, they have none against Rite Aid. Summary judgment is warranted.

BACKGROUND

Rite Aid Mid-Atlantic—the only Rite Aid entity named as a defendant in this case—is a distribution center that, up until late 2014, distributed controlled substances to Rite Aid pharmacies, including Rite Aid pharmacies in Ohio, where they were used to fill prescriptions written by medical professionals. Belli Dep. 20:13-16, Ex. A. Rite Aid Mid-Atlantic never distributed Schedule II controlled substances. Hart Dep. 37:9-13, Ex. F;

Rite_Aid_OMDL_0032602, Ex. L. The only drugs at issue in this case that Rite Aid Mid-Atlantic ever distributed are hydrocodone combination products (HCPs), a Schedule III opioid. Jena Rep. at 22, Ex. B. Rite Aid Mid-Atlantic ceased distribution of HCPs to Ohio in September 2014, a month before the DEA rescheduled HCPs to Schedule II. Belli Dep. 24:12-14, Ex. A. In late 2014, Rite Aid Mid-Atlantic stopped distributing all controlled substances entirely. Moore Decl. ¶ 6, Doc. 1703 at Ex. 7. Rite Aid Mid-Atlantic did not distribute to internet pharmacies; Rite Aid Mid-Atlantic did not distribute to “pill mills;” Rite Aid Mid-Atlantic distributed only to Rite Aid pharmacies. Jena Rep. at 24, Ex. B; Belli Dep. 20:13-16, Ex. A.

Rite Aid Mid-Atlantic was not a major distributor. From January 2006 until December 2014, Rite Aid Mid-Atlantic distributed less than one percent—████%—of the morphine milligram equivalents (MMEs)¹ distributed in Summit County and Cuyahoga County. Jena Rep. at 49, Ex. B. And during the limitations period (after April 2014), Rite Aid’s share was █████%, less than one-twentieth of one percent. Jena Decl. ¶ 2. Even as the total distribution of opioids to Cuyahoga and Summit Counties increased from 2006 to 2014, Rite Aid’s distribution of HCPs remained constant. Jena Rep. at 26-29, Ex. B.

During the time period that Rite Aid distributed opioids, it maintained effective controls against diversion. Jena Rep. at 14, Ex. B. These measures included inventory control, storing opioids in a locked and alarmed cage. Ringgold Dep. 66:9-24, 74:14-75:8, 115:1-14, Ex. D. Rite Aid conducted physical inventories twice each day and investigated any discrepancies. Ringgold

¹ Because opioids differ in potency, shipments of opioids are measured in MMEs to provide a standard way of measuring quantities across opioids. Jena Rep. at 11, Ex. B. The MME conversion factor converts the quantity of each drug into units that are equivalent to milligrams of morphine. Jena Rep. at 11, Ex. B.

Dep. 55:16-23, Ex. D. [REDACTED]

[REDACTED] Ringgold Dep. 52:8-53:8, Ex. D.

Rite Aid also employed order control and monitoring measures, including a shipment threshold (limiting the maximum size of shipments), an auto replenishment system (which calculated expected orders for pharmacies), and scheduled shipments (limiting the frequency of shipments). Rite Aid 2d Supp. Answers at 13, Ex. E, 15; Hart Dep. 79:21-80:14, Ex. F.

In addition, Rite Aid Hdqtrs. Corp.’s Asset Protection Department analyzed reports and data related to pharmacy orders. Rite Aid 2d Supp. Answers at 16, Ex. E. If the Asset Protection Department detected any anomalies in a pharmacy’s key performance indicators, it would initiate and complete an investigation into potential diversion. *Id.*, Ex. E.

Rite Aid’s controls were regularly audited by state and federal officials. For example, between 2005 and 2014, the Drug Enforcement Agency audited Rite Aid’s controls against diversion, including its suspicious order monitoring system, in four unannounced inspections and found no deficiencies. Jena Rep. at 21, Ex. B. In July 2012, during the last DEA inspection when Rite Aid still distributed controlled substances, the DEA inspectors specifically applauded its suspicious order monitoring system: “Both DEA inspectors are very impressed and pleased to see that Rite Aid demonstrates its due diligence by having an excellent excessive order monitoring system.” Rite_Aid_OMDL_0012547-49, Ex. G. Rite Aid received similar praise during earlier DEA inspections. In response to an inspection conducted in September 2005, DEA stated that it was a “flawless audit” and had “no words of advice . . . for improvement.” Rite_Aid_OMDL_0047171-72, Ex. G. In 2009, DEA commented, “Everything we saw meets the requirement of what we came to see. I’m happy, very happy.” Rite_Aid_OMDL_0012516-17, Ex. G.

Rite Aid's system passed similar inspections from the Maryland Division of Drug Control and Maryland Board of Pharmacy. Rite_Aid_OMDL_0016988-89, Ex. I; Rite_Aid_OMDL_0032614-17; Rite_Aid_OMDL_0032622-28; Rite_Aid_OMDL_0032629-33; Rite_Aid_OMDL_00326784-87, Ex. J. In 2012, the Maryland Division of Drug Control commented that the Rite Aid facility "has a good system for receipt and accountability of CDS [controlled dangerous substances]." Rite_Aid_OMDL_0036784-87, Ex. J.

Rite Aid also maintained a Verified-Accredited Wholesale Distributors ("VAWD") accreditation from the National Association of Boards of Pharmacy from 2007 through October 2014. Rite Aid 2d Supp. Answers at 17, Ex. E.

ARGUMENT

I. Plaintiffs' Failure to Present Evidence Regarding Rite Aid's Suspicious Monitoring System Requires Summary Judgment in Favor of Rite Aid.

Plaintiffs have no evidence that Rite Aid's distribution of opioids breached any duty because they have no evidence of deficiencies in Rite Aid's suspicious order monitoring system. Plaintiffs' partial motion for summary judgment regarding duties under the Controlled Substances Act confirms that the duty they seek to enforce against Rite Aid in this litigation is an alleged "duty to maintain effective controls against diversion" under the Controlled Substances Act. Mem. Support Pls.' Mot. Defs.' Duties at 3.

Proving that a defendant maintained an ineffective suspicious order monitoring system requires expert testimony. *Ramage v. Cent. Ohio Emergency Serv., Inc.*, 592 N.E.2d 828, 833 (Ohio 1992) ("Unless a matter is within the comprehension of a layperson, expert testimony is necessary."); *see also Thompson v. Bingham Greenebaum Doll LLP*, ---N.E. 3d---, 2019 WL 2308045, at *5 (Ohio App. May 24, 2019) (holding that expert testimony is required when "issues are not within the common knowledge of the layperson").

Recognizing this need for expert testimony, Plaintiffs designated Seth Whitelaw and James Rafalski as experts on suspicious order monitoring. But even if Whitelaw and Rafalski are permitted to testify,² they offered no opinions about Rite Aid’s suspicious order monitoring system. Nor did any other expert designated by Plaintiffs. Whitelaw analyzes the compliance controls employed by other distributors but not the controls employed by Rite Aid. At his deposition, Whitelaw confirmed that he had no opinion outside those disclosed in his report. Whitelaw Dep. 30:5-17, Ex. H. Similarly, Rafalski analyzes the suspicious monitoring systems of other distributors but not that of Rite Aid. Rafalski also confirmed that all of his opinions were disclosed in his report. Rafalski Dep. 664:18–665:3; 839:6-14, Ex. C.

With no expert testimony that there was any deficiency in Rite Aid’s suspicious order monitoring system, summary judgement must be granted in Rite Aid’s favor.

Only one expert has provided any analysis of Rite Aid’s suspicious order monitoring system: Dr. Anupam B. Jena, MD, PhD, who opined that Rite Aid Mid-Atlantic “maintained effective controls against diversion,” Jena Rep. at 14, Ex. B, and concluded that “Rite Aid Mid-Atlantic’s policies and procedures limited the risk of diversion and demonstrated effectiveness.” Jena Rep. at 19, Ex. B. Because Plaintiffs have offered no competing expert, Dr. Jena’s testimony stands unrebutted.

Indeed, Dr. Jena’s report reveals why Plaintiffs were unable to develop expert testimony criticizing Rite Aid’s suspicious order monitoring system: DEA regularly inspected the distribution center and in three unannounced DEA inspections of Rite Aid’s controls against diversion in 2005, 2009 and 2012, no deficiencies were found and Rite Aid was repeatedly praised,

² Defendants have filed *Daubert* motions challenging these experts.

including in July 2012 specifically for its “excellent excessive order monitoring system.” Rite_Aid_OMDL_0012547-49, Ex. G.

The uncontroverted evidence that Rite Aid Mid-Atlantic maintained effective controls against diversion is fatal to each of Plaintiffs’ claims.

II. Summary Judgment in Rite Aid’s Favor is Required on Causation.

Plaintiffs have presented no evidence that Rite Aid’s limited distribution of opioids caused any of their injuries.

Rite Aid distributed an exceptionally small amount of opioids to Cuyahoga and Summit Counties. During limitations period (after April 2014), Rite Aid distributed only [REDACTED] % of total MMEs. Jena Decl. ¶ 2. And in the period between January 2006 and December 2014, Rite Aid distributed only [REDACTED] %. Jena Rep. at 25, Ex. B.

There is no evidence that any of Rite Aid’s shipments within these tiny percentages were of suspicious orders; no evidence that any diversion occurred from any suspicious order shipped by Rite Aid; and no evidence that Plaintiffs suffered any injury traced to any diversion from any suspicious order shipped by Rite Aid.

Plaintiffs’ failure of proof is unsurprising, given that Rite Aid Mid-Atlantic distributed opioids only to Rite Aid pharmacies, where the opioids were used to fill lawful prescriptions. There is no evidence—or even an allegation—that Rite Aid Mid-Atlantic distributed opioids to internet pharmacies or pill mills.

Rite Aid distributed a small percentage of opioids for a brief time within the limitations period. Plaintiffs have no evidence showing that Rite Aid’s distribution of opioids had any statistically significant impact on the total volume of opioids in the two counties or that the harms

alleged would not have arisen if Rite Aid had not distributed opioids.³ Summary judgment is warranted in favor of Rite Aid.

A. Plaintiffs' Statutory Law Public Nuisance Claim Fails.

Plaintiffs' claim for statutory public nuisance rests on allegations that Rite Aid violated a "laws of Ohio or of the United States of America or [a] rule of the board of pharmacy controlling the distribution of a drug of abuse." Ohio Rev. Code § 4729.35; *see also* Ohio Rev. Code § 3767.01(C)(1). With no evidence of any deficiency in Rite Aid Mid-Atlantic's suspicious monitoring system, no evidence supports this claim.⁴

B. Plaintiffs' Common Law Public Nuisance Claim Fails.

Plaintiffs' claim of absolute public nuisance requires proof of interference with a public right either by: (1) an inherently dangerous activity, (2) intentional culpable conduct, or (3) unlawful conduct. *E.g., Barnett v. Carr*, No. CA2000-11-219, 2001 WL 1078980, at *10–11 (Ohio Ct. App. Sept. 17, 2001).

Without evidence of any deficiency in Rite Aid's suspicious order monitoring system (and uncontroverted evidence that Rite Aid maintained effective controls against diversion), Plaintiffs have no evidence that Rite Aid engaged in an inherently dangerous activity, culpable conduct

³ To the extent that Plaintiffs contend that they have suffered an indivisible injury, even if Plaintiffs could somehow present evidence tracing some injury to diversion from suspicious orders shipped by Rite Aid, given Rite Aid's extremely small percentage of the total distribution, Plaintiffs could not show that Rite Aid's conduct was a substantial factor in causing their injury. Proof of "substantial factor" causation requires more than evidence that a defendant may have contributed to a harm in some small degree. *Schwartz v. Honeywell International*, 102 N.E.3d 477, 481 (Ohio 2018); *see also* Restatement (Second) of Torts § 433, cmt. d (explaining that the combined effect of other contributing factors "may have such a predominant effect in bringing [the injury] about as to make the effect of the actor's negligence insignificant").

⁴ In addition, because Rite Aid stopped distributing opioids in September 2014, Plaintiffs cannot receive injunctive relief (the only available relief, Doc. 1203 at 30), and the claim is moot. *See, e.g., Ailor v. City of Maynardville*, 368 F.3d 587, 600 (6th Cir. 2004).

(intentional or otherwise), or unlawful conduct. This is particularly true given that Rite Aid distributed opioids only to its own pharmacies and distributed only a small percentage of the total opioids.

C. Plaintiffs' Negligence Claim Fails.

With no evidence that Rite Aid breached any duty to maintain effective controls against diversion, Plaintiffs cannot maintain a claim for negligence based on alleged breach of that duty.

D. Plaintiffs' Injury Through Criminal Acts Claim Fails.

Similarly, even accepting Plaintiffs' legal arguments on their own terms, Plaintiffs' claim for injury through criminal acts fails. Not only is there no evidence that Rite Aid “[b]y force, threat, or deception, administer[ed] to another or induce[d] or cause[d] another to use a controlled substance” or “administer[ed] or furnish[ed] to another or induce[d] or cause[d] another to use a controlled substance, and thereby cause[d] serious physical harm to the other person, or cause[d] the other person to become drug dependent,” Ohio Rev. Code § 2925.02(A)(3), but because there is no evidence of any deficiency in Rite Aid's diversion control system, Rite Aid falls within the safe harbor for “manufacturers, wholesalers, licensed healthcare professionals authorized to prescribe drugs, pharmacists, owners of pharmacies, and other persons whose conduct is in accordance with” state laws governing controlled substances. Ohio Rev. Code § 2925(B).

E. Plaintiffs' Claim for Unjust Enrichment Fails.

Finally, Plaintiffs' claim for unjust enrichment fails because it is based on the theory that Plaintiffs conferred a benefit by paying “the cost of the harms caused by Defendants' improper distribution practices.” Doc. 1203 at 38. With no evidence of any improper distribution practices by Rite Aid and uncontested expert testimony that Rite Aid maintained effective controls against diversion, Plaintiffs' unjust enrichment claim fails.

Because there is no genuine issue of material fact as to whether Rite Aid maintained effective controls against diversion, a fact which is fatal to all of Plaintiffs' claims alleging wrongdoing by Rite Aid,⁵ summary judgment is warranted.

CONCLUSION

Rite Aid fully agrees with the joint summary judgment motions detailing the general deficiencies in Plaintiffs' claims. This Court could grant summary judgment in favor of defendants on numerous grounds.

But even resolving all legal disputes in their favor, given the large number of defendants against whom Plaintiffs have chosen to bring suit, it was foreseeable (perhaps even inevitable) that Plaintiffs would fail to develop evidence supporting their claims against some defendants. And given Rite Aid Mid-Atlantic's small market share, it is unsurprising that Rite Aid is among those defendants. This Court should grant summary judgment in favor of Rite Aid on all claims against it.

Dated: June 28, 2019

Respectfully submitted,

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⁵ Plaintiffs' claims against Rite Aid must be based on wrongdoing by Rite Aid because, as detailed in Pharmacy Defendants' Motion for Summary Judgment on Plaintiffs' Civil Conspiracy Claim, there is no evidence supporting any conspiracy claim against Rite Aid.